

REMARKS**I. STATUS OF CLAIMS**

Claim 43 has been amended. Support for the amendment can be found throughout the specification and in particular at page 1, lines 6-14.

Claims 69-71 have been added. Support for the claims can be found throughout the specification and in particular at Figure 1 and page 1, lines 6-14.

After amending the claims as set forth above, claims 43-55 and 69-71 will be pending.

Claims 56-68 previously were withdrawn.

Applicant requests reconsideration of the application in view of the reasons that follow.

II. REJECTION UNDER 35 U.S.C. § 102

The examiner rejects claims 43, 48-52 and 54 under 35 U.S.C. § 102(b) for alleged anticipation by Niermann et al. Applicant respectfully traverses the rejection.

In levying the rejection, the examiner asserts, *inter alia*, that Niermann “teaches a ball housed within the socket, wherein at least part of an external surface of the ball in the socket is configured to contact the sample” and “introducing material...and rotating the ball on the said surface...and collecting the sample in the collection reservoir.” Office Action, pg. 3. These assertions are flawed factually, however.

As an initial matter, applicant notes that Niermann’s component #43 is not the “external surface of the ball”, as the examiner contends. Rather, component #43 corresponds to the open end of socket 40 which receives the ball 20.

Moreover, nothing in the cited material teaches collecting a sample in a collection reservoir by rotating a ball over the material, as the examiner suggests. In fact, the cited sections simply describe a modified lid to a test tube with a ball 20 in a socket 40, where the ball has a passageway 21 extending through its center. (column 4, lines 26-31). In the open

position (e.g. shown in Fig. 1), the passageway 21 allows the sample to be poured or pipetted through the ball 20 and into a collection tube 100. (column 4, lines 32-37). Once the tube 100 contains the sample, the ball 20 is then rotated such that passageway 21 is misaligned with the tube 100 thereby sealing the tube in a closed position (e.g. as shown in Fig. 2). Thus, Niermann's collection method involves pouring or pipetting a sample through the hole in the ball into a tube. (column 4, lines 32-37). Once the sample is introduced into the interior, the ball is rotated to seal the tube. (column 4, lines 36-38).

The cited portions of Niermann further teach that device features a seal 70, which isolates the top (environment contacting) external surface of ball 20 from collection tube 100. (column 8, lines 23-34). Niermann notes:

[r]otational movement of ball 20 within socket 40 about axle 30 accomplishes opening and closing of closure 10. For example, when closure 10 is in the closed position as shown in FIGS. 2, 8 and 9, environmental-contacting surface 27 is positioned within first open end 43 of ball receiving portion 90 and is exposed to the external environment while liquid-contacting surface 29 of ball 20 is positioned for exposure to 30 upper chamber 115 of collection tube 100. The external surface of ball 20 contacts elastomeric seal 70 in a sealing engagement, thus **preventing any fluid contained within collection tube 100 from passing beyond elastomeric seal 70 and between ball 20 and socket 40.** (column 8, lines 23-34, emphasis added).

Niermann notes further that:

[a]n operator's finger engages tab 22 of ball 20, and applies pressure to tab 22 in a direction toward environmental-contacting surface 27. Such pressure transmits a force to ball 20 about axle 30, thus causing ball 20 to rotate about axle 30 within socket 40. This rotative movement causes liquid-contacting surface 29 to 40 engage elastomeric seal 70, and the continuous rotative movement of ball 20 provides for a **wiping action** between elastomeric seal 70 and liquid-contacting surface 29. Accordingly, **any blood or other contaminant which is present on liquid-contacting surface 29 is wiped from the surface thereof by elastomeric seal 70.** (column 8, lines 34-45, emphasis added).

From this passage it is clear that Niermann's device does not collect a sample through contact with the **external**, environment-contacting surface 27 of ball 20. Any material from the environment contacting surface 27 would be sealed off from the collection tube 100,

and/or wiped away by rotation of the ball 20. Thus, contrary to the examiner's assertion that Niermann teaches "rotating the ball on said surface...and collecting the sample in the collection reservoir," the cited portions of Niermann teach the use of a sample collection device such that a sample is poured or pipetted through an **interior** passageway of the device.

Meanwhile, the claimed methods involve collecting a sample using a device providing, *inter alia*, a ball housed within a socket such that at least part of an external surface of the ball is configured to contact the sample. Thus, the material is introduced into the device by contacting the material with the external surface of the ball and then rotating the ball. Niermann's cited methods completely lack such a feature. To emphasize this point, applicant has amended the claims to recite that the sample material is contacted with the external surface of the ball.

As Niermann fails to disclose each and every element of the recited methods, it cannot anticipate the claims. The rejection, therefore, should be withdrawn.

III. REJECTION UNDER 35 U.S.C. § 103

The examiner rejects claims 43-47 as being unpatentable over Niermann in view of Sharpe. Claims 43, 50, 52-53 and 55 also are rejected as being unpatentable over Niermann in view of Shuber. Applicant traverses the rejections.

As noted above, Niermann fails to teach a method of collecting a sample using a device providing, *inter alia*, a ball housed within a socket such that at least part of an external surface of the ball is configured to contact the sample. Neither Sharpe, cited for allegedly disclosing a sample collection device containing an absorbent material housed within a collection reservoir, or Shuber, cited for allegedly teaching collection of biological samples and employing a thermocycler to analyze DNA, cure the deficiencies of the primary reference. Thus, no combination of the cited material yields the claimed methods. For this reason alone, the obviousness rejection must fail.

Yet, the rejection fails on other grounds, too. In particular, no motivation for formulating a sample collection method as claimed is apparent from the cited material. For

example, the examiner asserts that a practitioner would have been motivated to combine Niermann's ball and socket device with Sharpe's absorbent material to reabsorb and retain large volumes of liquid released from the ball. (Office Action, pg. 6). Yet, as noted above, Niermann does not teach collecting a sample through contact with the external surface of a ball. Thus, no additional benefit would be obtained by compressing an absorber against the external surface of the ball, as the examiner suggests.

Accordingly, applicant submits that the examiner has not established a *prima facie* case of obviousness and requests withdrawal of the rejection.

Applicant requests an early indication that this application is in allowable condition. Examiner Bhat is invited to contact the undersigned directly should he feel that any issue requires further consideration.

The Commissioner is hereby authorized to charge any additional fee which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17 and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, then applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of the relevant fee from the deposit account.

Respectfully submitted,

Date

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